IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

TINA BURRIS,

Plaintiff,

v.

ETHICON, INC., et al.,

Defendants.

CASE NO. 3:20 CV 1450

JUDGE JAMES R. KNEPP II

MEMORANDUM OPINION AND ORDER

INTRODUCTION

Currently pending before the Court are Defendants Ethicon, Inc. and Johnson & Johnson's: (1) Motion and Supplemental Motion to Exclude the Case-Specific Opinions and Testimony of Niall Galloway, M.D. (Docs. 39, 95), (2) Motion to Exclude the Case-Specific Opinions and Testimony of Robert Tremp, Jr., MA, CRC, CLCP, LAC (Doc. 41), and (3) Supplemental Motion for Partial Summary Judgment (Doc. 96). Also pending is Defendants' Motion to Strike Dr. Galloway's Supplemental Affidavit. (Doc. 101). These matters are fully briefed and ripe for decision.

For the reasons discussed below the Court grants Defendants' Motion to Strike (Doc. 101); grants Defendants' Supplemental Motion for Partial Summary Judgment (Doc. 96), grants in part and denies in part Defendants' Motion and Supplemental Motion to Exclude Dr. Galloway's Case-Specific Opinions and Testimony (Docs. 39, 95), and denies Defendants' Motion to Exclude Mr. Tremp's Case-Specific Opinions and Testimony. (Doc. 41).

BACKGROUND

Plaintiff is among a group of individuals who brought suits against Defendants for injuries allegedly stemming from Defendants' pelvic mesh medical devices. Specifically, on August 5, 2008, Ms. Burris underwent implantation of the Gynecare Prolift and Gynecare TVT-Secur ("TVT-S") in a surgery performed by Dr. Desrene Brown in Bluffton, Ohio. (Doc. 15, Plaintiff Fact Sheet, at 6). The Prolift was intended to treat pelvic organ prolapse, and the TVT-S was intended to treat stress urinary incontinence. *See id*. Dr. Mark Walters removed a portion of the Prolift mesh in Cleveland in November 2011. *Id.* at 7-10. Plaintiff suffers from pelvic and buttock pain and she has difficulty walking, sitting, or standing for lengthy periods of time. *Id.* at 7. Dr. Niall Galloway, Plaintiff's expert witness urologist, opines that Plaintiff suffers from "pudendal neuralgia and/or muscle damage causing groin, leg, and vaginal pain; chronic, long term and life altering pelvic pain; dyspareunia; and painful bladder filling syndrome". (Galloway Report, at 20)[1].

At this point, two legal claims remain under the Ohio Product Liability Act, directed at both the TVT-S and the Prolift: failure to warn (Count III) and design defect (Count V). The facts relevant to each pending motion will be discussed in conjunction with those motions.

STANDARD OF REVIEW

Summary judgment is appropriate where there is "no genuine issue as to any material fact" and "the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). When considering a motion for summary judgment, the Court must draw all inferences from the record in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith*

1. Dr. Galloway's Report is located at numerous places in the record, including at ECF Doc. 39-1, at 2-33. Dr. Galloway's deposition is similarly located at numerous places in the record, including at ECF Doc. 39-1, at 45-69.

Radio Corp., 475 U.S. 574, 587 (1986). The Court is not permitted to weigh the evidence or determine the truth of any matter in dispute; rather, the Court determines only whether the case contains sufficient evidence from which a jury could reasonably find for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248-49 (1986). The moving party bears the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). This burden "may be discharged by 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support the nonmoving party's case." *Id*.

DISCUSSION

Defendants argue they are entitled to summary judgment on some of Plaintiff's remaining claims. Related to these issues, Defendants move to strike Dr. Galloway's Supplemental Affidavit, filed with Plaintiff's opposition to summary judgment. Defendants further contend this Court should exclude or limit the opinions of two of Plaintiff's expert witnesses – Dr. Galloway and Mr. Tremp – at trial. The Court addresses these contentions in turn.

Supplemental Motion for Partial Summary Judgment (Doc. 96)

Defendants first argue they are entitled to summary judgment on Plaintiff's failure to warn claim as it relates to the TVT-S because Plaintiff cannot prove an injury from that product. Second, they assert Plaintiff's design defect claim fails in its entirety – both as it relates to the TVT-S and as to the Prolift – because Plaintiff has failed to present evidence of an alternative design. For the reasons discussed below, the Court grants Defendants' Motion.

Defendants' Motion to Strike (Docs. 101, 102)

The Court turns first to Defendants' Motion to Strike (Docs. 101, 102), as a determination thereon necessarily informs the Court's summary judgment rulings. Defendants move to strike the Affidavit of Dr. Galloway (Doc. 99-4) submitted by Plaintiff in conjunction

with her opposition to Defendants' motion for partial summary judgment. They contend the Affidavit should be stricken because it is untimely, is not true "supplementation", and Plaintiff has not shown excusable neglect or good cause.

Plaintiff responds Dr. Galloway's Affidavit "serves to update Dr. Galloway's opinions based on the new information gleaned from the Dr. Conway medical records." (Doc. 103, at 5). She argues it is proper and timely supplementation under Civil Rule 26. Alternatively, she argues any failure to timely supplement was substantially justified and harmless under Rule 37.

The Federal Civil Rules provide "[a] party who has made a disclosure under Rule 26(a) . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." Fed. R. Civ. P. 26(e)(1)(A). Even setting aside preliminarily Defendants' additional arguments that Dr. Galloway's affidavit is not "supplementation" as envisioned by the rules, for the following reasons, the Court finds Dr. Galloway's Affidavit is not "timely" supplementation.

By way of background, in August 2020, after the case was remanded from the MDL to this Court, Plaintiff saw Mark Conway, M.D., for an examination. (Doc. 99-3). Dr. Conway summarized Plaintiff's medical history, and on examination diagnosed: "pudendal neuralgia[,] possible left-sided ilioinguinal neuralgia, [and] some elements of obturator neuralgia as well." *Id.* at 4. On examination he observed that "the TVT mesh is very tender to palpation" and opined the "TVT mesh is also a significant pain generator contributing to her bladder symptoms as well." *Id.* He recommended complete removal of the TVT mesh. *Id.*

Plaintiff asserts Dr. Galloway's Affidavit was based on new information, namely the two-page medical record from Dr. Conway's August 31, 2020 examination that Plaintiff obtained on November 11, 2020. *See* Doc. 99-3. However, Dr. Galloway's Affidavit is dated almost three full months later, on February 5, 2021. *See* Doc. 99-4. During this same time period, Defendants indicated to the Court (and to Plaintiff) their desire to file a supplemental partial summary judgment motion and the parties described the potential need for additional fact discovery. *See* Doc. 80 (August 17, 2020 Report of Parties' Planning Meeting); Doc. 83 (October 16, 2020 Joint Status Report in which Plaintiff advised a surgeon had recommended removal of the TVT-S). On November 20, 2020, Defendants filed a motion for leave to file a supplemental partial summary judgment motion (Doc. 85); they attached the proposed motion (Doc. 85-1). In the motion for leave itself, Defendants argued Plaintiff lacked necessary expert proof regarding a safer alternative design for either product and lacked any proof of injury regarding the TVT-S. *See* Doc. 85. These arguments were directed specifically at alleged gaps in proof from Dr. Galloway's original report and deposition testimony. On December 10, 2020, Plaintiff filed her opposition to the motion for leave. (Doc. 88). Therein, she raised only procedural arguments regarding the timing and appropriateness of such a supplemental motion. *Id.* Five days later, the parties filed a Court-ordered Joint Status Report regarding additional discovery. (Doc. 90). Therein, Plaintiff again noted a surgeon recommended removal of the TVT-S, but had been unable to follow up or have the recommended surgery due to the COVID-19 pandemic. *Id.* at 2. Defendants did not believe additional discovery was necessary and Plaintiff stated she "may request leave to conduct discovery from the additional providers once their records have been reviewed." *Id.* Plaintiff did not mention any intention to submit records to Dr. Galloway, or to ask Dr. Galloway to supplement his expert report based thereupon.

On January 6, 2021, this Court granted Defendants' motion for leave to file a supplemental partial summary judgment motion; Defendants did so the following day – making the arguments previously outlined. (Docs. 94, 96). On February 5, 2021, Plaintiff filed a timely response to that motion, attaching the new Galloway Affidavit – dated the same day. (Docs. 99, 99-4).

Given this sequence of events, the Court cannot find the Galloway Affidavit – submitted almost three full months after a two-page medical record was acquired – to be "timely" supplementation under the Rule. *See* Fed. R. Civ. P. 26(e)(1)(A) (requiring supplementation "*in a timely manner* if the party learns that in some material respect the disclosure or response is incomplete or incorrect") (emphasis added). Although Plaintiff asserts Dr. Galloway "needed time to review the records and supplement his opinion based on Dr. Conway's records", she does not explain why review and analysis of a two-page medical record would take from November 2020 to February 2021.

Plaintiff next contends that even if the Court finds Dr. Galloway's Affidavit not a timely supplemental opinion, the failure to timely supplement was substantially justified and harmless under Federal Civil Rule 37. "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1).[2] The Sixth Circuit counsels that a Court consider five factors to evaluate harmlessness:

2. "[T]he burden is on the potentially sanctioned party to show harmlessness." *U.S. ex rel. Tennessee Valley Auth. v. 1.72 Acres of Land In Tennessee*, 821 F.3d 742, 752 (6th Cir. 2016); *see also Saint Gobain Autover USA, Inc. v. Xinyi Glass N. Am., Inc.*, 666 F. Supp. 2d 820, 826 (N.D. Ohio 2009) ("The party requesting exclusion under Rule 37(c)(1) need not show prejudice,

> (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence.

Howe v. City of Akron, 801 F.3d 718, 748 (6th Cir. 2015) (quoting *Russell v. Absolute Collection Servs., Inc.*, 763 F.3d 385, 396–97 (4th Cir. 2014)). The Court has "broad discretion in applying these factors and need not apply each one rigidly." *Bisig v. Time Warner Cable, Inc.*, 940 F.3d 205, 219 (6th Cir. 2019) (internal quotation and citation omitted). "The factors simply lend themselves to the task at the heart of Rule 37(c)(1): separating 'honest,' harmless mistakes from the type of 'underhanded gamesmanship' that warrants the harsh remedy of exclusion." *Id.* (quoting *Bentley v. Highlands Hosp. Corp.*, 2016 WL 5867496, at *10 (E.D. Ky.) (quoting *Howe*, 801 F.3d at 747, 749 (internal citations omitted))).

The first factor – surprise – weighs against Plaintiff and in favor of excluding the Affidavit. Although Plaintiff asserts Defendants were aware of Dr. Conway's records since November 11, 2020, Defendants were *not* on notice that Plaintiff intended to submit that record to Dr. Galloway and obtain a supplemental expert opinion. This distinction is relevant because Defendants made clear in their November 20, 2020 motion for leave that they intended to seek summary judgment based on asserted gaps in proof in Dr. Galloway's expert opinion and deposition testimony. Knowing this, Plaintiff did not – despite numerous opportunities – provide Defendants any notice she planned to have Dr. Galloway supplement his expert opinions in a manner to address those asserted deficiencies.

The second and third factors – ability to cure surprise and trial disruption – weigh in favor of permitting the Affidavit. This case was remanded from the MDL to this Court in July

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rather the non-moving party must show that the exclusion was 'harmless' or 'substantially justified.'").

2020, and, in light of the pending supplemental partial summary judgment motion and the COVID-19 pandemic, this case is not yet set for trial. Plaintiff asserts Defendants can cure any surprise "by supplementing their own expert's report". (Doc. 103, at 11).

The fourth factor – the importance of the evidence – cuts both ways to some degree. That is, the more important the proof, the greater the effect of preclusion, but also the greater the harm in an untimely disclosure. In particular, without Dr. Galloway's supplemental Affidavit – as Defendants identify in their motion for partial summary judgment – Plaintiff's proof was allegedly lacking in several respects. Thus, from Plaintiff's perspective (particularly as to her claim regarding the TVT-S), the evidence was important. From Defendants' perspective, however, permitting such a late disclosure results in wasted time preparing a motion, and possibly additional effort and expense required in seeking leave to file new motions based on the new evidence.

Finally, the Court finds the fifth factor – the party's explanation for its failure to disclose the evidence – weighs against admitting the Affidavit. First, Plaintiff's actions and timing, as described above, undermine their stated – otherwise somewhat reasonable – explanation. Plaintiff's actions and timing appear more like the "gamesmanship" the Rule 37 exclusion remedy is designed to prohibit. Had Plaintiff sought leave to obtain a supplemental expert affidavit in light of the new records, or notified Defendants of her intent to do so earlier, the Court would have been inclined to permit her to supplement. Specifically, after receiving Defendants' Motion for Leave, Plaintiff could have informed Defendants and this Court that she wished to supplement her expert report, in an attempt to address some or all of the alleged defects in her case, rather than simply making procedural arguments against allowing leave. Instead, she simply submitted the Affidavit, without seeking leave, and without any notice to

Defendants. The Affidavit also appears – at least to some extent – crafted in a way to address the potentially claim-ending defects first identified by Defendants almost three months earlier. As Defendants point out, Dr. Galloway's Affidavit goes beyond the allegedly new information provided by Dr. Conway's visit. That is – for the first time, Dr. Galloway states he has relied on expert Dr. Blaivas's general causation opinions. (Doc. 99-4, at 2, 5). Dr. Blaivas's report was issued prior to Dr. Galloway's original report, and Dr. Galloway's original report does not reference it as a basis for his opinions. Moreover, Dr. Galloway identifies new alternative designs to the Prolift that he had not previously identified – "[t]he Prosima or a cut to fit polypropylene mesh used in the treatment of [pelvic organ prolapse] would eliminate the risk of combined pudendal and obturator neuralgia which Ms. Burris suffers" (Doc. 99-4), without a rationale for why these alternative designs could not have been identified in his original report.

On balance, the consideration of these factors leads the Court to conclude Dr. Galloway's untimely supplemental Affidavit is less like an "honest, harmless mistake" and more like "the type of underhanded gamesmanship that warrants the harsh remedy of exclusion." *Bisig,* 940 F.3d at 219 (internal quotation and citation omitted). Therefore, the Court finds it appropriate to exercise its discretion and grant Defendants' Motion to Strike Dr. Galloway's Affidavit.

Failure to Warn

Defendants contend they are entitled to summary judgment on Plaintiff's failure to warn claim as it relates to the TVT-S because Plaintiff has no evidence of injury connected to the device. In response, Plaintiff relies on Dr. Galloway's supplemental Affidavit – based on Dr. Conway's examination – as proof that the TVT-S has caused Plaintiff injury. However, the Court has stricken that supplemental affidavit for the reasons described above.

To prevail on a failure to warn claim under Ohio law, a plaintiff must prove three elements: (1) a duty to warn against reasonably foreseeable risks; (2) breach of this duty; and (3) an injury proximately caused by the breach. *Graham v. Am. Cyanamid Co.*, 350 F.3d 496, 514 (6th Cir. 2003). A plaintiff must present expert medical testimony to establish causation when she asserts a specific physical injury, the cause for which is not within common knowledge. *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994); *Laderer v. St. Rita's Med. Ctr.*, 122 Ohio App. 3d 587, 599 (1997) (finding "expert testimony is needed on complex issues outside the area of common knowledge, such as an injury's cause and effect"); *see also Botnick v. Zimmer, Inc.*, 484 F. Supp. 2d 715, 724 (N.D. Ohio 2007) ("To prove proximate causation for medical conditions or illnesses allegedly caused by a defective product, a plaintiff must show by a reasonable degree of medical certainty that the disease or injury was caused by the defective product.") (citing cases).

When questioned at his deposition, Dr. Galloway testified he could not "directly relate" a specific symptom to the TVT-S, could not say the TVT-S "has in the past caused problems" for Plaintiff, but believed "so long as that midurethral polypropylene mesh sling is in place, there is a potential in the future for it to cause problems." (Galloway Depo., at 45-46). Without evidence of injury proximately caused by the TVT-S, Plaintiff has no claim regarding the TVT-S. Defendants' Motion for Summary Judgment on Plaintiff's failure to warn claim – as it relates to the TVT-S – is therefore GRANTED.

Design Defect

The parties also dispute whether Plaintiff can satisfy the requirement to show a feasible alternative design to overcome summary judgment on her design defect claim. Defendants contend this claim fails – as to both the Prolift and the TVT-S – because the alternatives

identified by Dr. Galloway are not alternative designs for the medical devices, but rather entirely different procedures. Plaintiff argues Dr. Galloway's identification of biologic tissue alternatives meet – or at least create an issue of material fact about – this element of the claim.

Under Ohio design defect law, a plaintiff must prove "a practical and technically feasible alternative design" to the product at issue was available. Ohio Rev. Code. § 2307.75(F) ("A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product."). "Ohio law requires expert testimony where aspects of the defect or the proposed alternative designs are technically complex and outside the understanding of a lay juror." *Newell Rubbermaid, Inc. v. Raymond Corp*., 676 F.3d 521, 529–30 (6th Cir. 2012) (citing *Atkins v. Gen. Motors Corp.,* 132 Ohio App. 3d 556, 564 (1999) (explaining that expert testimony is "often . . . necessary," particularly where the product at issue is complex))).

In his report, Dr. Galloway says:

> To a reasonable degree of medical certainty, Ms. Burris' injuries would not have occurred with alternative surgical intervention such as the Burch procedure, native tissue repair, or colpopexy. In addition, there were biologic materials, including autologous grafts, allografts and xenografts that would have been safer alternatives and would have alleviated the complications suffered by Ms. Burris.

(Doc. 39-1, at 22) (Galloway Report, at 21). In his deposition, Dr. Galloway identified a paravaginal repair as the alternative surgical option to the Prolift. (Galloway Depo., at 65) (stating he would not perform a native tissue colporrhaphy in Plaintiff's circumstances, but "you would do a paravaginal repair that would restore normal pelvic support anatomy without sacrificing any of the vaginal capacity or function.").

Defendants assert the alternatives identified by Dr. Galloway – the Burch procedure, native tissue repair, and colpopexy – are not alternative designs, but rather, alternative medical procedures. Citing case law, they argue this is insufficient to show an alternative design. (Doc. 96-1, at 5-6). Plaintiff, in response, does not argue this point, but focuses on Dr. Galloway's identification of autologous grafts, allografts, and xenografts. She contends these are "slings constructed from an alternative material to polypropylene—specifically, biologic tissue." (Doc. 99, at 5). She says that "[l]ike a synthetic mid-urethral sling, autologous, allograft, and xenograft slings are placed under the urethra to help support[] the pelvic floor muscles and help the urethra resist increases in abdominal pressure transmitted to the bladder." *Id.*[3] Defendants contend Dr. Galloway's opinions on biologic alternatives such as allografts and xenografts are insufficient for Plaintiff to proceed with her claim because (1) Dr. Galloway does not say these products would have prevented Plaintiff's injuries, and (2) biologic alternatives do not qualify as an alternative design to polypropylene mesh products such as the TVT-S. (Doc. 96, at 6). They further contend Plaintiff has failed to provide *any* design alternative to the Prolift as the biologic slings identified are for the treatment of stress urinary incontinence, not pelvic organ prolapse. (Doc. 100, at 2).

The Court finds Defendants' second argument dispositive. At base, the question is whether biologic alternatives can satisfy the standard for "a practical and technically feasible alternative design". Ohio Rev. Code § 2307.75(F). The MDL court explained "an alternative, feasible design must be examined in the context of products—not surgeries or procedures".

3. Plaintiff does not point to where this description exists in Dr. Galloway's report or his deposition, nor cite anything for these statements. Indeed, Dr. Galloway's report says only what is quoted above – that "there were biologic materials, including autologous grafts, allografts and xenografts that would have been safer alternatives". (Doc. 39-1, at 22) (Galloway Report at 21). Nor has the Court found any further elaboration in Dr. Galloway's deposition regarding these proposed alternatives.

Mullins v. Johnson & Johnson, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017). Elaborating, the court explained:

> Evidence that a surgical procedure should have been used in place of a device is not an alternative, feasible design in relation to the TVT. Whether an alternative procedure could have been preformed [sic] without the use of the TVT does nothing to inform the jury on the issue of an alternative, feasible *design* for the TVT. Instead, alternative surgeries or procedures raise issues wholly within the context of what a treating physician has recommended for patients based on the individual needs and risk factors associated with individual patients. In other words, alternative surgeries or procedures concern the medical judgment of the doctors who use TVT devices to treat stress urinary incontinence ("SUI"); other surgeries or procedures do not inform the jury on *how* the TVT's design could have feasibly been made safer to eliminate the risks that caused the plaintiffs' injuries.

Id.

Relying in part on this analysis, in *Willet v. Johnson & Johnson*, another district court examined the same issues and arguments presented to this Court – specifically the argument that biological alternatives are regulated differently than medical "products":

> The Willets concede that native tissue repairs do not qualify as "safer alternative designs," because they are not products, but they argue that allografts and xenografts do qualify, because they are products. *See* Pl.'s Brief [Dkt. No. 61], 4 n.1. The Willets argue that Dr. Zipper's opinions about allografts and xenografts are relevant to the risk-utility analysis required under Iowa law and to counter any evidence from Ethicon that Prosima was the safest and most effective means of treating POP. They argue that the main difference between allografts or xenografts and Prosima is that such tissue grafts use a natural material rather than a synthetic material.
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> This court agrees with the MDL court that, as a general matter, "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. MDL 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017); *accord Mullins v. Johnson & Johnson*, 236 F. Supp. 3d 940, 942 (S.D.W. Va. 2017) ("I am convinced that an alternative, feasible design must be examined in the context of products—not surgeries or procedures.") (citing *Talley v. Danek Med., Inc.*, 179 F.3d 154 (4th Cir. 1999)). This is so, because "[w]hether an alternative procedure could have been performed without the use of the [device] does nothing to inform the jury on the issue of an alternative, feasible design for the [device]." *Mullins*, 236 F. Supp. 3d at 943. The choice of a surgery over a

> device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product. *Id.* Thus, the Willets must provide "sufficient evidence to identify a comparable product or design concept" to generate a jury question on the sufficiency of the alternative, feasible design. *Id.* at 944. I agree with the defendants that allografts and xenografts are not "comparable products" or "comparable design concepts" to the Prosima device, when, for example, allografts are regulated by the FDA as human tissues for transplantation, *see* 21 C.F.R. Part 1271, and xenografts are regulated as biological products for transplantation, *see* FDA Guidance Document: Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans at 7. Neither is classified as a medical device, like Prosima.
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> Thus, Dr. Ripper's opinions about allografts and xenografts are not relevant or reliable, because they do not relate to an alternative product or alternative design concept for a product. *In re: Ethicon, Inc.*, 2016 WL 4493681, at *2–3.

465 F. Supp. 3d 895, 907–08 (S.D. Iowa 2020).

Plaintiff points to no specific evidence – from Dr. Galloway or otherwise – explaining how Dr. Galloway's citation of "autologous grafts, allografts and xenografts" (Galloway Report, at 21), are a specific alternative design for the medical devices at issue here. Further, like many other courts have, this Court agrees with the above analysis from the MDL court and the *Willet* court regarding biologic alternatives, and alternative procedures. *See, e.g., Lim v. Ethicon, Inc.*, 2021 WL 612399, at *5 (S.D. Miss.) ("From the record, it does not appear that the TVT-O could be modified to be an autologous fascial sling, as such a sling does not involve any implantation of a medical device."); *Moultrie v. Coloplast Corp*., 2020 WL 1249354, at *11 n.20 (W.D. Pa.) (noting autologous fascia sling and Burch colposuspension "appear to be medical procedures rather than medical devices" and expert "did not address the issue of how [defendant] could have 'modified' its Aris device by abandoning it altogether in favor of a surgical procedure"); *Salinero v. Johnson & Johnson*, 2019 WL 7753453, at *17 (S.D. Fla.), *reh'g denied*, 2019 WL 7753439 (finding surgical procedures such as biological grafts are not alternative designs to synthetic pelvic mesh products, and thus excluding testimony that

autologous fascia lata and allografts are "safer alternative designs"); *Cofresi v. Medtronic, Inc*., 450 F. Supp. 3d 759, 766 (W.D. Tex. 2020) ("The example of biomesh 'made from natural or compatible organic tissue' is not an 'alternative' to Prolene Mesh; it is an entirely different product. And the reality is that Plaintiff's surgeon made the decision to use the Prolene Mesh; that Plaintiff now believes biomesh would have been a better choice does not mean that it is an "alternative" under the law.") (internal citations omitted); *Burton v. Ethicon Inc.,* 2020 WL 5809992, at *4 (E.D. Ky.) ("The Court agrees that evidence regarding a surgical procedure not involving mesh has no bearing on the existence of a safer alternative design for the defendants' Prolift product. Accordingly, evidence regarding such procedures is not admissible to prove the existence of safer alternative designs."); *Owens v. Ethicon, Inc.*, 2020 WL 1976642, at *3 (E.D. Ky.) ("While the alternative procedures and treatment options identified by Dr. Fogelson may have been legitimate ways to address Ms. Owens' condition, these alternatives have no bearing on the elements of a design defect claim.").

The Court finds the cases cited by Plaintiff to support a contrary finding distinguishable or unpersuasive. In *Johns v. C.R. Bard (In re Davol, Inc*.), the court found identification of specific porcine-based products that were "on the market"– where the expert "cites to literature and studies in support of each proposed alternative" – sufficient to show an alternative design to polypropylene hernia mesh. 2020 WL 6605542, at *24 (S.D. Ohio) (identifying the "XenMatrix®AB,187 comprised solely of noncrosslinked porcine acellular dermal matrix bioprosthetic" and the "Zenapro® Hybrid Repair Device which combines a large pore lightweight polypropylene mesh sandwiched between two layers of porcine small intestinal submucosa"). Plaintiff presents no such specific "product" or design alternative.

And in *Pizzitola v. Ethicon, Inc.*, the court found "alternatives . . . that were made of human or animal tissues" were sufficient alternative designs to survive summary judgment, but did not confront the argument presented above as to the differing regulations regarding medical products and human or animal tissue. 2020 WL 6365545, at *5 (S.D. Tex.). For this same reason, *Christopher v. DePuy Orthopaedics, Inc. (In re DePuy Orthopaedics, Inc.)* – finding a plastic hip implant and a metal hip implant were not substantially different products – is distinguishable. 888 F.3d 753, 767-68 (5th Cir. 2018). Nor is Plaintiff's citation to *Darwish v. Ethicon*, 2020 WL 7129582 (N.D. Ohio) persuasive. There, in response to a motion to dismiss, the court found Plaintiff entitled to proceed on her design defect claim where "the Complaint raise[d] a plausible inference that a practical and feasible alternative design does exist: a pelvic mesh product not containing polypropylene mesh" and asserted broadly that there were "available feasible alternatives that do not involve the same risks." 2020 WL 7129582, at *5. That case was at the motion to dismiss stage, rather than the summary judgment stage and the plaintiff did not yet have to provide admissible evidence regarding a specific alternative design.

Another district court in this circuit confronted a similar issue regarding polyester hernia mesh under Michigan law. It explained:

> The Michigan Supreme Court has not addressed when a proposed alternative is a different product rather than a feasible alternative production practice. But several other jurisdictions have addressed when a proposed alternative is too far removed from the challenged product to constitute an alternative design. *See Hosford v. BRK Brands, Inc.*, 223 So. 3d 199, 205–08 (Ala. 2016) (collecting cases). In jurisdictions requiring plaintiffs to prove the existence of a safer alternative design, "a design for a different, albeit similar, product" will not suffice, "even if it serves the same purpose." *Id.* at 208.

Barnes v. Medtronic, PLC, 2019 WL 1353880, at *2 (E.D. Mich) (footnote omitted) (finding Plaintiff's "proposed alternatives are alternative treatment methods or alternative types of mesh, not alternative production practices or designs for polyester hernia mesh").

Based on all of the above, this Court thus finds that the "autologous grafts[4], allografts and xenografts" identified by Dr. Galloway cannot satisfy the "practical and technically feasible alternative design" required by Ohio Rev. Code § 2307.75(F) because, at base, they are not different designs for the medical product polypropylene mesh products at issue here, but rather completely different procedures subject to completely different regulations.

The Court finds Plaintiff has not presented evidence to create a genuine issue of material fact as to her design defect claim. Defendants' Motion for Summary Judgment on Plaintiff's design defect claim is therefore GRANTED.[5]

Daubert Challenges

Next, the Court turns to Defendants' challenges to Plaintiff's expert witnesses.

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and the Supreme Court's seminal cases of *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993) and *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999). *See United States ex rel. Tenn. Valley Auth. v. 1.72 Acres of Land in Tenn.*, 821 F.3d 742, 748-49 (6th Cir. 2016). Rule 702 provides expert testimony is appropriate when it will "help the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a). Experts are only permitted to testify, however, when "(b) the testimony is based on sufficient facts or data; (c) the testimony is the product of

4. Indeed, Dr. Galloway himself characterizes an autologous facia sling as an "alternative surgical option[] that include[s] non-mesh-based techniques". (Galloway Report, at 18).

5. In his supplemental Affidavit, Dr. Galloway says – for the first time – that "[t]he Prosima or a cut to fit polypropylene mesh used in the treatment of [pelvic organ prolapse] would eliminate the risk of combined pudendal and obturator neuralgia which Ms. Burris suffers." (Doc. 99-4, at 5). Because the Court grants Defendants' Motion to Strike the Affidavit, the Court need not reach this issue, which Defendants address in Reply. *See* Doc. 100, at 2. Moreover, Plaintiff – in her brief opposing Defendants' motion for partial summary judgment – does not rely on these proposed alternatives (despite attaching the Affidavit), but points only to Dr. Galloway's opinions regarding autologous grafts, allografts, and xenografts. *See* Doc. 99, at 7-10.

reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702.

Under Rule 702, "a proposed expert's opinion is admissible, at the discretion of the trial court, if the opinion satisfies three requirements. First, the witness must be qualified by 'knowledge, skill, experience, training, or education.' Second, the testimony must be relevant, meaning that it 'will assist the trier of fact to understand the evidence or to determine a fact in issue.' Third, the testimony must be reliable." *In re Scrap Metal Antitrust Litig.,* 527 F.3d 517, 528–29 (6th Cir. 2008) (quoting Fed. R. Evid. 702). A court's inquiry should focus solely on principles and methodology, not on the conclusions they generate. *Daubert,* 509 U.S. at 595. Courts should confirm "the factual underpinnings of the expert's opinion [are] sound," *Greenwell v. Boatwright,* 184 F.3d 492, 498 (6th Cir. 1999), but generally "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence", *Daubert,* 509 U.S. at 596. "Rule 702 should be broadly interpreted on the basis of whether the use of expert testimony will assist the trier of fact." *Morales v. Am. Honda Motor Co.,* 151 F.3d 500, 516 (6th Cir. 1998). "Mere weaknesses in the factual basis of an expert witness's opinion . . . bear on the weight of the evidence rather than on its admissibility." *McLean v. 988011 Ontario, Ltd.,* 224 F.3d 797, 801 (6th Cir. 2000).

Additionally, *Daubert* provided a non-exhaustive checklist of factors to determine the reliability of expert testimony. These factors include: "testing, peer review, publication, error rates, the existence and maintenance of standards controlling the technique's operation, and general acceptance in the relevant scientific community. . . ." *United States v. Langan,* 263 F.3d 613, 621 (6th Cir. 2001) (citing *Daubert,* 509 U.S. at 593–94). However, the *Daubert* factors

"are not dispositive in every case" and are applied only "where they are reasonable measures of the reliability of expert testimony." *Gross v. Comm'r*, 272 F.3d 333, 339 (6th Cir. 2001).

Finally, the district court may, but is not required to hold a hearing to address a *Daubert* issue. *See Greenwell*, 184 F.3d 492, 498 (6th Cir. 1999).

Dr. Galloway

Dr. Galloway is Plaintiff's designated case-specific expert regarding causation.

General Causation Opinions

Defendants first ask the Court to exclude Dr. Galloway's "general causation" opinions because Dr. Galloway was disclosed as a case-specific expert, rather than a general causation expert. (Doc. 40, at 4-5). In conjunction, they ask the Court to exclude testimony by Dr. Galloway about complications not relevant to Plaintiff's injuries. *Id.* Defendants specifically contend Dr. Galloway's opinion contains "approximately 18 pages of general causation opinions" regarding defects in synthetic mesh devices, and complications associated therewith. (Doc. 40, at 4). Plaintiff does not dispute that a case-specific causation expert may not offer general causation opinions, but contends Dr. Galloway is providing the background scientific support for his ultimate differential diagnosis in this case and thus the content of his report should be admitted in full. (Doc. 51, at 6-8).

Generally, "[t]he distinction between general and specific causation experts is a procedural tool to aid in the streamlining of discovery and the filing of *Daubert* motions." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4958297, at *1 (S.D.W. Va.). Where an expert is designated as a case-specific causation expert, his expert testimony concerning causation must be tailored to only the specific causation opinions concerning the case at hand. That said, such testimony "may necessarily include elements of general causation

related to [the] specific causation opinions." *Id.* Additionally, the MDL court explained that "[e]vidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value." *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, at *5 (S.D.W. Va.).

The Court agrees with these principles set forth by the MDL court. At trial, Plaintiff's counsel must tailor Dr. Galloway's expert testimony to only include his causation opinions applicable to Plaintiff's case, consistent with the Court's below findings on Defendants' more specific challenges. *See In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 7242550, at *2 (S.D.W. Va.) ("Ethicon also argues that Dr. Galloway provided general causation testimony in addition to specific causation testimony regarding the individual plaintiff at bar. Dr. Galloway was not designated and disclosed as a general causation expert. . . . At trial, counsel must tailor Dr. Galloway's expert testimony to only his specific causation opinions applicable to Ms. Harter's case."). However, Dr. Galloway may offer testimony regarding the scientific basis for his differential diagnosis, so long as that testimony relates to injuries Plaintiff herself suffered. The Court reserves for trial ruling on more specific relevance objections Defendants may raise.

Legal Conclusions, Terms of Art

Second, Defendants ask the Court to exclude Dr. Galloway's opinions to the extent they contain legal conclusions, terms of art, and improper opinions regarding Ethicon's state-of-mind. (Doc. 40, at 5-6). Specifically, they point to Dr. Galloway's statements in his report that introducing transvaginal mesh products into the marketplace violated the medical principle of "Do No Harm", and caused a "predictable" "public health crisis". (Galloway Report, at 2). They further object to Dr. Galloway's statements that (1) Plaintiff's injuries "were foreseeable", and

(2) the products are "unreasonably dangerous" because the risks outweighed the benefits and because Ethicon "misrepresent[ed]" the potential complications. (Galloway Report, at 29-31). Plaintiff responds Dr. Galloway's expert report does not offer legal conclusions or improperly use legal terms of art. She further asserts she is "well-aware of the Court's prior rulings on [state-of-mind] issues and does not intend for Dr. Galloway to offer" any such opinions. (Doc. 51, at 10).

The Court agrees with Defendants that Dr. Galloway's statements that Defendants violated the medical principle of "Do No Harm", and caused a "predictable" "public health crisis" (Galloway Report, at 2) should be excluded as not relevant or helpful to the jury. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013) ("Bard's knowledge, state of mind, alleged bad acts, failures to act, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury."). Similarly, Dr. Galloway's statement that a product was "unreasonably dangerous" is excludable. *See Sederholm v. Boston Sci. Corp*., 2016 WL 3282587, at *2 (S.D.W. Va.) ("An expert may not state his opinion using 'legal terms of art,' such as 'defective,' 'unreasonably dangerous,' or 'proximate cause.'"); *Wise v. C.R. Bard, Inc.,* 2015 WL 521202, at *5 n.4 (S.D.W. Va.) ("Dr. Ostergard opines that the purported omissions in the Avaulta IFU 'rendered [the device] not reasonably safe.' This opinion invades the province of the jury by stating a legal conclusion and will not be accepted at trial.") (internal record citation omitted). On the other hand, Defendants do not explain why Dr. Galloway may not offer an opinion on the foreseeability of Plaintiff's injuries. The Court agrees that if this opinion touches on Defendants' knowledge or state of mind, it is excludable. Although he may not testify to what Defendants did

or did not know, Dr. Galloway may testify to why he believes Plaintiff's injuries were foreseeable.

Defendants argue broadly that Dr. Galloway's report "contains numerous opinions stating legal conclusions and standards and using legal terms of art, as well as improper opinions regarding Ethicon's state of mind and corporate conduct." (Doc. 40, at 5) (citing, *generally*, Dr. Galloway's entire report). The Court has addressed the specific language identified by Defendants, and will not independently search through Dr. Galloway's report. Plaintiff acknowledges – and says she will follow – the MDL court's prior instructions regarding legal conclusions and state-of-mind, and Defendants can raise any additional objections at trial.

Warnings / Informed Consent

Third, Defendants ask the Court to exclude Dr. Galloway's opinions regarding warnings and informed consent. (Doc. 40, at 6-7). They contend Dr. Galloway is not qualified to render expert opinions regarding the adequacy of warnings, and his opinions on such are irrelevant and improperly touch on Defendants' state-of-mind. Defendants also argue Dr. Galloway's opinion improperly – and unhelpfully – addresses Plaintiff's implanting physician's personal knowledge. Plaintiff responds Dr. Galloway "is more than qualified to testify as to whether the IFUs address the risk of injuries like those suffered by Plaintiff and whether a doctor is able to obtain informed consent in the absence of such information." (Doc. 51, at 11).

Defendants point specifically to the following statements from Dr. Galloway:

(1) "I have reviewed the relevant Instructions for Use. In my opinion, the warnings provided in the IFUs do not provide doctors with the information needed to make treatment choices and obtain informed consent from their patients." (Galloway Report, at 21).

(2) "In my opinion, the TVT-S and Prolift devices used in Ms. Tina Burris were unreasonably dangerous because the risks far outweighed the benefits, Ethicon did not warn doctors and patients of the serious risks, and Ethicon made

> inaccurate and misleading representations as to the safety of the devices. These devices were unreasonably dangerous because Ethicon did not provide Ms. Tina Burris or her doctors with accurate and complete information and warnings. (Galloway Report, at 30-31).

The MDL Court explained: "[w]hile an expert who is a urologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.,* 2016 WL 4961675, at *3 (S.D.W. Va.). However, "an expert who is a urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.,* 2016 WL 4536885, at *2 (S.D.W. Va.); *see also In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.,* 2011 WL 6301625, at *11 (S.D. Ill.) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . .") (internal quotations omitted).

Here, Plaintiff has not shown Dr. Galloway has additional expertise regarding the drafting of IFU documents. Rather, she argues only Dr. Galloway's experience as a urologist who "counsels his patients in exactly this matter [risks versus benefits] on a daily basis" renders him "more than qualified to opine as to what information is necessary for his patients to have prior to consenting to treatment." (Doc. 51, at 11-12). Other courts have rejected such reliance on an expert's experience as a physician to provide the "additional expertise" regarding what should be in an IFU document. *See, e.g., Block v. Ethicon, Inc.*, 2020 WL 6440516, at *4 (S.D. Ind.) ("None of Dr. Margolis's admittedly extensive experience extends into the field of drafting IFU warnings, however. Without such expertise, he is not qualified to testify regarding what warnings, if any, are required relating to an IFU."); *Meade v. Ethicon, Inc.,* 2020 WL 6395814,

at *6 (E.D. Ark.) ("While Dr. Walmsley has demonstrated his competency to testify about the risks associated with TVT-Os and related devices, that expertise does not equate to expertise regarding the product IFUs and the adequacy of the warning information contained therein."); *see also Wiltgen v. Ethicon, Inc*., 2017 WL 4467455, at *8 (N.D. Ill.) ("Dr. Elliott may give testimony on the TVT's IFU, but the testimony must be limited to his area of expertise, and his opinions must not involve legal or regulatory matters.").

Therefore, Dr. Galloway, based on his experience, may testify to the risks of mesh as are relevant to this case – and whether those specific risks appeared on the IFU, but will not be permitted to testify as to what warnings are required to be included in an IFU.

Relatedly, Defendants further contend Dr. Galloway should not be permitted to testify the warnings provided on the IFU prevented the implanting physician from obtaining informed consent from Plaintiff. They contend such an opinion is "simply a restated opinion that Ethicon's warning . . . were inadequate" and "effectively opin[es] as to the [implanting] physician's personal knowledge (or lack thereof) at the time of [Plaintiff's] surgery." (Doc. 40, at 7). Dr. Galloway opines in his report that the implanting physician could not obtain informed consent based on the warnings provided in the IFU. The Court agrees with Defendants that in these circumstances, such an opinion is tantamount to a restated opinion that the product warnings were inadequate, which is a legal conclusion and the province of the jury. Therefore, his opinion will be excluded in this regard. *See Meade*, 2020 WL 6395814, at *6 (holding testimony from a urologist regarding the informed consent process "would operate to provide a restated opinion that Ethicon's warnings for the TVT-O were inadequate"); *see also Simpson v. Johnson & Johnson*, 2020 WL 5630036, at *4 (N.D. Ohio) ("Dr. Brennan's opinion that 'the mesh lacked

adequate warnings to physicians' about risks of complications is an inadmissible legal conclusion.")

Dr. Galloway testified he had not spoken to Plaintiff's implanting physician and had not read her deposition testimony. (Galloway Depo., at 66-67). The basis for his testimony about what risks the implanting physician – Dr. Brown – did or did not know was a conversation he had with Plaintiff's attorneys summarizing Dr. Brown's deposition. *Id.* at 67. Defendants argue that allowing such testimony effectively opines as to the physician's personal knowledge at the time of Plaintiff's surgery, which is not helpful. *See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.,* 2016 WL 4493457, at *3 (S.D.W. Va.) (excluding testimony "on what 'all physicians' know or should know or what 'all physicians' rely on in making informed decisions); *see also Arevalo v. Colplast Corp.*, 2020 WL 3958505, at *12 (N.D. Fla.), *reconsideration denied*, 2020 WL 6018933 ("Dr. Rosenzweig is not qualified to opine on the state of mind of Plaintiff or her implanting surgeon, as he does in his specific causation report."). This Court agrees that Dr. Galloway may not testify regarding the knowledge of other physicians. The jury is capable of listening to Dr. Brown's testimony in conjunction with Dr. Galloway's testimony to determine the risks of which Dr. Brown was or was not aware.

Harm from TVT-S

Fourth, Defendants initially contended this Court should preclude Dr. Galloway from offering an opinion that Plaintiff has been harmed – or may be harmed – by the TVT-S. Because the Court above grants Defendants' Motion for Summary Judgment on all of Plaintiff's claims regarding the TVT-S, Dr. Galloway's opinions regarding the device will be excluded as irrelevant.

Alternative Surgical Procedures / Non-Mesh Alternatives

Fifth, Defendants move to exclude Dr. Galloway's opinions and testimony regarding alternative surgical procedures because they cannot constitute feasible alternative designs under Ohio law and because these alternatives do not eliminate the risk of injuries Plaintiff suffered. (Doc. 95-1, at 4-11). For the reasons discussed, the Court grants Defendants' motion for summary judgment on Plaintiff's design defect claims, therefore Dr. Galloway's opinions regarding such alternatives will be excluded as irrelevant.

Infection in Prolift Mesh

Finally, Defendants move to preclude Dr. Galloway from offering an opinion that exposed mesh is, by definition, colonized with bacteria and infected, or that Plaintiff's Prolift mesh was itself infected or caused Plaintiff any infection. Defendants point to the following testimony from Dr. Galloway:

> Q: Do I understand correctly that the mesh exposure found on September 17th, 2008, you believe to have been the Prolift mesh?
>
> A: Yes.
>
> Q: Is that based on the location?
>
> A: Well, the location is not a given. And so we do not - - we do not have information about just exactly what this is. But we do know that subsequent to the problems of pain and dyspareunia became much more marked and we do know that on subsequent examination she had not one but two areas of exposure of the mesh within the anterior vaginal wall. And we have very detailed information about it from Dr. Walters at the Cleveland Clinic who was the surgeon who was responsible for trying to remove this infected, exposed anterior vaginal mesh, which was the anterior Prolift.
>
> Q: What evidence, if any, do you have suggesting that the mesh that Dr. Brown removed in September 2008 was infected?
>
> A: By definition, if the mesh is exposed on the surface, it is colonized and infected. And the - - the Defendant Exhibit Number 4 that I have brought

> with me today clearly lays out the natural history of this problem and provides you with more than 150 references in the literature that relate to the mechanisms of candida infection, many of which have to do with prosthetic infections.
>
> Q: Do you believe that the mesh exposure was the result of an infection?
>
> A: No. I believe the mesh exposure is a complication of mesh placement that is directly related to the design of the anterior Prolift mesh and that it is capable, as in this case, of breaking the surface of the vagina. And when it breaks the surface of the vagina, it is equivalent, but much worse than having the product no longer wrapped and no longer sterile in the operating room.
>
> Germs like to be dark and warm and moist. And all of these conditions exist not only in the human mouth, but also in the human vagina. And it is impossible to have exposed mesh in the vagina as we have in this case and not have the underlying polypropylene mesh be colonized with organisms. And that results in deep tissue infection and that results in the surgical challenge of trying to remove this kind of infected, inflamed, vaginal mesh.

(Galloway Depo., at 56-58).

Defendants attack Dr. Galloway's opinion that exposed mesh in the vagina is "by definition" colonized and infected and that it is "impossible" to have mesh exposure without colonization as unreliable. Specifically, they assert the article cited by Dr. Galloway at his deposition does not support his testimony. (Doc. 40, at 11) ("Indeed, the word 'mesh' is not even mentioned in the body of the article or its references section."). Relatedly, they contend Dr. Galloway should be precluded from offering any testimony that Plaintiff suffered any mesh-related infection because – they assert – Dr. Galloway did not include such a conclusion in his expert report. (Doc. 40, at 13) (citing Fed. R. Civ. P. 26(a)(2)(B) (requiring an expert report contain "a complete statement of all opinions the witness will express")). Plaintiff responds that the cited article supports Dr. Galloway's "general proposition regarding the formation of

biomaterial on exposed medical devices and resulting infection in such devices" and that Dr. Galloway cites other literature to support his infection opinion in his report. (Doc. 51, at 15-16).

As Defendants point out, the MDL court addressed expert testimony on a related point. In *Sanchez v. Boston Scientific Corp.,* an expert sought to offer an opinion that the infection rate in polypropylene mesh implantation is "up to 100%". 2014 WL 4851989, at *11 (S.D.W. Va.). The Court explained its exclusion of such opinion evidence:

> However, as BSC points out, the study which Dr. Margolis cites to support his 100% figure is not directly applicable. The *Boulanger* study did not find that 100% of the mesh systems explanted for the study were infected; the study found that 100% of the mesh systems were contaminated with bacteria. (*See* Margolis Report [Docket 58–1], at 16; Boulanger et al., *Bacteriological Analysis of Meshes Removed for Complications After Surgical Management of Urinary Incontinence or Pelvic Organ Prolapse,* 19 Int'l Urogynecol J. 827, 827 (2008) [Docket 58–5]). The authors of the *Boulanger* study are not certain that bacteria contamination leads to infection. (*See* Boulanger, *supra,* at 827, 830) (stating that the "exact role" of bacterial contamination "is not yet clear" and "must be explored by other experimental studies")). They even write that "[i]nfection is a rare complication of retropubic mid-urethral slings (0.7% of cases)" and that their "findings concur with previously published data" on this subject. (Boulanger, *supra,* at 830).
>
> The *Boulanger* study does not support the opinion that there is a 100% infection rate in women who undergo mesh implantation surgery. Therefore, Dr. Margolis's methodology of basing his opinion on this study is unreliable. As a result, Dr. Margolis's opinion as to infection rates is **EXCLUDED.**

Id. at *17.

Plaintiff contends that – unlike in the *Sanchez* case – here "Dr. Galloway did not make any such sweeping contention that 100% of all mesh implantation surgeries result in infection, and Defendants' efforts to characterize his opinion as such are misleading." (Doc. 51, at 16). This is true. But Dr. Galloway did make a similarly "sweeping contention" that exposed mesh is "by definition" infected. And, similar to the *Sanchez* case, "the study which [Dr. Galloway] cites to support his [exposure necessarily means infection] opinion is not directly applicable." *Id.* The introduction to that study explains:

> A biofilm consists in a community of microorganisms that are irreversibly attached to a given surface, inert material, or living tissue, producing extracellular polymers that provide a structural matrix. The microorganisms in this type of community exhibit lower growth rates and higher resistance to antimicrobial treatment, behaving very differently from planktonic cells. The ability to adhere to different types of surfaces enables microorganisms to form biofilm on medical devices, such as intravascular catheters, prosthetic heart valves and joint replacements or in different tissues in the host, linking biofilms to persistent colonization and infections.

Mafalda Cavalhiero & Miguel Cacho Teixeira, *Candida Biofilms: Threats, Challenges, and Promising Strategies*, 5 Frontiers in Medicine 28 (February 2018) (Doc. 39-1, at 71-85). Defendants are correct that this study does not address mesh specifically and does not, in and of itself, support Dr. Galloway's opinion that exposed mesh is necessarily infected.

Plaintiff's argument regarding Dr. Galloway's other cited sources is no more persuasive. She contends that "[w]hen specifically discussing potential contamination and infection of synthetic mesh devices, Dr. Galloway cites to no fewer than eight different sources in his report and overall, he cites to hundreds of medical articles in his reference materials." (Doc. 51, at 16) (citing Galloway Report, at 3-4). But even Plaintiff herself characterizes this evidence as supporting "*potential* contamination and infection". She explains, citing Dr. Galloway's opinion, that the cited studies show synthetic mesh is "resistant to antibiotics and host defenses" and that infection "has been found in as few as 31% and as high as 96% of cases involving the vaginal implantation of propylene mesh. " *Id.* She then concludes that "Dr. Galloway's opinion regarding infection is based on his own clinical experience and supported by multiple studies and relevant medical literature, including many that discuss infection in polypropylene mesh specifically." *Id.* While Dr. Galloway's opinion certainly cites literature regarding the *risk* of infection in polypropylene mesh and the reasons therefor, nowhere does Plaintiff explain how this literature supports Dr. Galloway's deposition testimony that "[b]y definition, if the mesh is exposed on the

surface, it is colonized and infected. (Galloway Depo., at 57). As such, Dr. Galloway may not offer such an opinion at trial.[6]

Defendants also seek to preclude Dr. Galloway from testifying Plaintiff's Prolift mesh was infected, or that she suffered any infection as a result of the Prolift, citing Federal Civil Rule 26's requirement that an expert report contain "a complete statement of all opinions the witness will express", and Dr. Galloway's summary of Plaintiff's "mesh related injuries" as including "pudendal neuralgia and/or muscle damage causing groin, leg, and vaginal pain; chronic, long term and life altering pelvic pain; dyspareunia; and painful bladder filling syndrome", but not "infection" specifically (Galloway Report, at 20). Plaintiff responds that "[a]s Dr. Galloway discussed in his deposition, Plaintiff's medical records indicate that she was treated for vaginal infection on August 20, 2008, only two weeks after she was implanted with the polypropylene mesh products. As established in his Report, Dr. Galloway testified that such infection is likely caused by erosion and mesh exposure through the wall of the vagina." (Doc. 51, at 17-18) (citing Galloway Report, at 3-4; Galloway Depo., at 55-58).

Preliminarily, the Court finds Plaintiff's description inaccurate. Although Plaintiff cites Dr. Galloway's deposition testimony regarding a vaginal infection two weeks after her surgery, Dr. Galloway testified he believed that infection was caused by pre-surgery antibiotics:

> Q: You mentioned, I believe, that Dr. Brown treated Miss Burris on August 20th, 2008, for what she believed was an active vaginal infection; is that right?
>
> A: That's correct.
>
> Q: And [to] what, if anything, do you attribute that vaginal infection?

6. As such, the Court need not reach Defendants' argument that Dr. Galloway's opinion should be excluded because it fails to account for contradictory literature regarding mesh infection. However, to the extent Dr. Galloway testifies – as he describes in his report – to the *risk* of infection, Defendants may certainly cross-examine him regarding any such contrary literature.

> A: Well, it's very common when antibiotics are given that the antibiotics kill off not only pathogenic or disease-causing organisms, but it will also kill off the friendly organisms that effectively take up space on the coverings of the skin and the vagina.
>
> So, for example, if an antibiotic is given for a urinary tract infection, which is commonly the situation, it's not uncommon for some patients having lost the normal organisms in the vagina which are called lactobacilli. There will be an overgrowth of the competing organisms which are not sensitive to the antibiotic and that would be the population that make up yeast and other nonbacterial organisms.
>
> So in this case the most likely cause for her overgrowth of vaginal candida is having been subject to the administration of antibiotics for her surgical procedure two weeks before.

(Galloway Depo, at 54). That is, he did not testify "that such infection is likely caused by erosion and mesh exposure through the wall of the vagina" as Plaintiff asserts. (Doc. 51, at 17-18).

However, Dr. Galloway's testimony – also cited by Plaintiff – is illuminating as to his analysis of infection as it relates to this case:

> And when these products come into the operating room, they come double-wrapped with sterile labels on them and warnings that the mesh should not be used if the packaging has been disturbed, because these permanent implantable meshes have to be used in a sterile field. If they are not used in a sterile field, or if they subsequently become exposed on the surface, they become colonized with particularly the candida organism, which then creates a biofilm that travels on the mesh product and goes deeply into the tissues over time and causes a very well-known pattern of pain and inflammation and scarring and distortion of the tissues.
>
> And this is true whether the implant is a pacemaker or a hip replacement or vaginal mesh. And it is this constellation of events in this case where we have mesh placement, we have a vaginal candida infection, we have an in-office procedure where the mesh is trimmed[.] [T]hat is like taking a piece of a splinter in your skin and taking the scissors and cutting the tip of it off, the part that's protruding from the skin – the part that causes the problems, the part that is deep in the tissues and that marks the start of natural history with which we're very familiar, which leads to chronic pain and a pattern of problems that is very clearly seen here in Miss Tina Burris.

(Galloway Depo., at 55-56). Although Dr. Galloway did not specifically list "infection" as one of Plaintiff's "mesh related injuries" in the summary paragraph cited by Defendants, he did elsewhere list "recurrent vaginal mesh exposures" (Galloway Report, at 29) as one of Plaintiff's "mesh-related complications", and elsewhere described the risk of infections and complications associated with infections related to such exposures (e.g., chronic inflammation, pain, functional bladder problems) (Galloway Report, at 3-4). And in his summary of Plaintiff's "injuries", he states that these injuries "are the direct result of the defects/features/properties of the TVT-S and/or Prolift devices discussed in this report." (Galloway Report, at 20); *see also* Galloway Report, at 29 ("These injuries are the direct result of the defects inherent in these devices, including source of chronic inflammation, foreign body reaction, shrinkage, deformation, scarring and fibrosis, hardening, nerve damage, and degradation of the polypropylene mesh"). This, combined with Dr. Galloway's explanation in his opinion regarding the vaginal environment, and the properties of polypropylene mesh and infection risk, provides a sufficient basis for Dr. Galloway to offer an opinion that he believed Plaintiff to have suffered an infection and the Court finds this opinion is reasonably read as contained in his Report. However, as above, he will not be permitted to opine that Plaintiff's mesh was necessarily infected because it was exposed in the vagina.

Mr. Tremp

Next, Defendants move to exclude the report of Robert Tremp, Jr., MA, CRC, CLCP, LAC in its entirety as unreliable, beyond the scope of his qualifications, and not helpful to the jury. (Doc. 42). Plaintiff responds that Defendants' challenges go to the weight, rather than admissibility of Mr. Tremp's opinion.

Mr. Tremp has a Master's Degree in Special Education and Rehabilitation Counseling. (Doc. 41-1, at 116). He is a Certified Life Care Planner, Certified Rehabilitation Counselor, and Licensed Associate Counselor. *Id.* He reviewed Plaintiff's medical records, Dr. Galloway's report, and interviewed Plaintiff before offering a Vocational Report outlining Plaintiff's ability to work and loss of earning capacity, and a Life Care Plan regarding Plaintiff's future needs. *See* Doc. 41-1. Mr. Tremp describes a Life Care Plan as follows:

> A Life Care Plan is a dynamic document based upon published standards of practice, comprehensive assessment, data analysis, and research, which provides an organized and precise plan for current and future needs with associated costs for individuals who have experienced a catastrophic injury or have chronic health care needs. The goals of a Comprehensive Life Care Plan are to improve and maintain the clinical state of the patient, prevent secondary complications, provide support for the family, and to provide a disability management program aimed at preventing unnecessary complications and minimizing the long-term care needs of the patient.

Id. at 20.

Defendants first contend Mr. Tremp's vocational opinion – that Plaintiff is unable to work – lacks a reliable foundation because Dr. Galloway (upon whose medical opinion Mr. Tremp relies in part), "does not opine, to a reasonable degree of medical certainty, that [Plaintiff] is unable to work solely [due] to the injuries that he attributes to the Profift." (Doc. 42, at 4). They contend that without such an opinion, Mr. Tremp cannot opine that Plaintiff's mesh-related injuries alone have rendered her completely and permanently unable to work. But, as Plaintiff argues, Defendants point to no authority for the assertion that a vocational opinion must be based on a medical opinion that an individual is disabled. Mr. Tremp relied on Plaintiff's medical records – including Dr. Galloway's case-specific report – as well as an interview with Plaintiff to evaluate her vocational abilities and limitations. Defendants do not directly challenge Mr. Tremp's methodology or his qualifications to opine on vocational issues, but rather the

underlying facts he considered (or did not consider). The Court finds these challenges go to the weight or persuasiveness of Mr. Tremp's testimony, not its admissibility. *See Daubert*, 509 U.S. at 596 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."); *see also McLean*, 224 F.3d at 801 ("Mere weaknesses in the factual basis of an expert witness's opinion . . . bear on the weight of the evidence rather than on its admissibility.").

Second (and relatedly), Defendants contend Mr. Tremp's vocational opinions are unreliable "due to his failure to consider directly relevant evidence that contradicts the opinions set forth in his Vocational Report." (Doc. 42, at 5). Specifically, they contend Mr. Tremp failed to consider (1) Plaintiff's other medical conditions and the extent to which Plaintiff's inability to work may be based in part thereon, and (2) the Social Security Administration's contrary determination that Plaintiff was capable of alternate employment. But again, the Court finds this question goes to the weight and persuasiveness of Mr. Tremp's opinion, rather than its reliability. *See Smith v. Carbide & Chems. Corp.*, 2009 WL 5184342, *2 (W.D. Ky.) (the existence of potentially contrary facts are "a proper matter for cross-examination, but do[] not render [the expert's] opinions unreliable."); *United States v. Davis*, 103 F.3d 660, 674 (8th Cir. 1996) (noting defendant was "free to challenge the expert's conclusions and point out the weaknesses of the [expert's] analysis to the jury during cross-examination" but "[w]eight and credibility are the province of the jury.").

Third, Defendants contend Mr. Tremp's opinion regarding Plaintiff's loss of earning capacity is not helpful to the jury because the resulting calculation is a mere "common sense estimate". (Doc. 42, at 8) ("Mr. Tremp's opinion regarding lost earning capacity is an estimate

based on common sense—she earned approximately $24,960 per year before she quit her job; she is no longer able to work, so she earns $0 per year; therefore, her 'loss of earning capacity' is $24,960 per year."). Plaintiff contends that it is "common and acceptable practice for plaintiffs to rely on an experienced vocational rehabilitation expert to present evidence as to future earnings". (Doc. 50, at 8).

The Court will permit Mr. Tremp to testify about Plaintiff's lost earning capacity. Although the resulting calculation may be a simple one, it is connected to Mr. Tremp's expertise and explanation regarding his opinion that Plaintiff cannot work, and that her prior job salary was her pre-injury earning capacity. *See WWP, Inc. v. Wounded Warriors Fam. Support, Inc.*, 628 F.3d 1032, 1040 (8th Cir. 2011) ("There is not, as WWFS suggests, an implicit requirement in Fed. R. Evid. 702 for the proffered expert to make *complicated* mathematical calculations.") (citing *In re Prempro Prods. Liab. Litig.*, 514 F.3d 825, 831 (8th Cir. 2008) (holding district court did not abuse its discretion in failing to exclude expert testimony that represented "an exercise in basic math using simple deductive reasoning")).

Fourth and finally, Defendants contend Mr. Tremp's Life Care Plan is unreliable due to lack of foundation and should be excluded. Plaintiff responds that Mr. Tremp's Life Care Plan is well-founded and reliable. She further asserts that although Defendants seek to exclude Mr. Tremp's Life Care Plan entirely for lack of medical foundation, much of that Plan does not include care of the type that must be prescribed by a medical doctor. Finally, she notes that where Mr. Tremp's Plan addresses future medical care, he makes clear that those assessments are based on Dr. Galloway's report and Plaintiff's medical records.

The MDL court explained, regarding life care plans specifically:

> To be admissible, Ms. Latham's opinions and life care plan must be based on "reliable principles and methods" reliably applied to the facts of this case.

> Fed.R.Evid. 702. Because much of Ms. Latham's life care plan describes particular medical procedures and services, there must be a medical foundation for her recommendations. In other words, a doctor or medical expert must opine to a reasonable degree of medical certainty that the items listed in the life care plan are necessary.

In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig., 2014 WL 186872, at *12 (S.D.W. Va.).

Mr. Tremp's Life Care Plan includes descriptions and cost estimates for items and services he asserts Plaintiff will require including: rehabilitation/long-term needs assessment, psychological evaluation, physical therapy evaluation, individual counseling, a power scooter and accompanying maintenance and equipment, a rollator/walker, home safety equipment (tub and toilet safety rails, stander security poles, bed rail, power lift recliner), incontinence supplies, over-the-counter medication, home care assistance (housekeeping and lawn care/maintenance, treatment and evaluation by a primary care physician, urologist, urogynecologist, and pain management specialist. (Doc. 41-1, at 41-49). For his recommendations for future medical care (including physical therapy and physician treatment and evaluations), Mr. Tremp notes he bases these recommendations on Dr. Galloway's statement that Plaintiff "will require life-time medical and non-medical services throughout her life expectancy" combined with his own research. *See id.*; Galloway Report, at 21.

Preliminarily, the Life Care Plan in this case differs – at least in degree – from the one addressed by the MDL court. In that case:

> Ms. Latham's report provides a comprehensive summary of services that she opines that Ms. Lewis will require. For example, Ms. Latham projects that Ms. Lewis and her husband will require psychological and sexual therapy evaluations for the next twenty-four years. (*See id.* at 117). Ms. Latham also projects that Ms. Lewis will require various medical supplies; drugs, such as Ambien, Citalopram, Hydrocodone, and Valium; and specific surgical procedures, such as Botox injections to the bladder, Coaptite injections to the bladder and sphincter, and "future mesh related surgery interventions for incontinence." (*Id.* at 117–18). Ms. Latham originally opined that Ms. Lewis will need an ATV with a rifle mount and

> a truck ramp for the ATV, (*id.* at 31), but she has since removed this item from her amended report.

In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig., 2014 WL 186872, at *11.

By contrast here, Mr. Tremp does not offer an opinion that Plaintiff will require any specific ongoing medical treatment, specific prescription drugs, or specific surgery.[7] Rather, he offers opinions regarding various medical evaluations to then determine future treatment – based on his own experience, Plaintiff's medical records, Dr. Galloway's report, and specifically on Dr. Galloway's opinion that Plaintiff will require lifetime care. The Court finds generally that Mr. Tremp is qualified to give these opinions and Defendants objections go to the weight of the testimony rather than its admissibility.

Defendants argue broadly that "[b]ecause no doctor has opined that the services and items in Mr. Tremp's Life Care Plan are medically necessary, his Life Care Plan and related opinions should be excluded as unreliable." (Doc. 42, at 9). However, other than objecting to the line item regarding a power scooter and related costs ("For example, Dr. Galloway has not opined that [Plaintiff's] injuries have rendered her immobile." (Doc. 42, at 9)), Defendants have not offered specific arguments regarding each item in the Life Care Plan and why it requires a "medical necessity" determination. Defendants do not challenge Mr. Tremp's resulting calculations for each item on the Life Care Plan, only – again, broadly – the underlying foundation for the Plan in its entirety.

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7. Mr. Tremp's Life Care Plan includes line items "for information purposes only" regarding the cost of radiofrequency ablation of the pudendal nerve, and "Additional Surgical Intervention (To Be Determined)." (Doc. 41-41, at 48-49). These are certainly "specific medical procedures" and Mr. Tremp will not be permitted to testify regarding their cost absent evidence adduced at trial that they are medically recommended. *See In re Ethicon, Inc., Pelvic Repair Sys. Prod. Liab. Litig.,* 2014 WL 186872, at *12

The Court finds the items listed in Mr. Tremp's Life Care Plan sufficiently within his expertise and grounded in the record. Mr. Tremp's determination that Plaintiff may need a rehabilitation assessment, psychological evaluation, individual counseling, a scooter and rollator walker and various accessories, home safety items, incontinence supplies, a housekeeper, lawn care/maintenance assistance, and over-the-counter medication are within Mr. Tremp's areas of expertise as a Certified Life Care Planner, Certified Rehabilitation Counselor, and Licensed Associate Counselor. *See, e.g., Smithers v. C&G Custom Module Hauling*, 172 F. Supp. 2d 765, 773 (E.D. Va. 2000) (overruling objection to life care planning expert's inclusion of home and yard maintenance, and home assistance, even when some of those items were described as merely being "really good for" the plaintiff, and finding "[s]uch arguments may have merit, but on balance they go to the weight, not the admissibility of the proposed evidence"); *Roach v. Hughes*, 2015 WL 3970739, at *3 (W.D. Ky.) (permitting life care planner to testify where she "based her opinions on sufficient facts and data, including Ms. Roach's medical records, the opinions and recommendations of Ms. Roach's multiple treating medical providers, her consultation with Ms. Roach, and her own research on Ms. Roach's condition"); *Boden v. United States*, 2019 WL 6883813, at *5 (W.D. Va.) ("[C]ourts . . . have found that life-care plans can be admissible without a physician review, so long as they are reliable."); *Burress v. Winters*, 2010 WL 2090090, at *1 (D. Md.) (permitting a life care plan without physician review and finding that "numerous courts have permitted non-physicians to opine about future medical needs, even when their opinions are not supported by the recommendations of a physician"); *Deramus v. Saia Motor Freight Line, LLC*, 2009 WL 1664084, at *2 (M.D. Ala.) (permitting life care planner testimony where life care Planner "testified that her proposed life care plan was based on a review of Plaintiff's medical records, depositions taken from Plaintiff's physicians, and

numerous meetings with Plaintiff" and finding "any objection to [the] opinions must go to the weight the jury should give to her testimony rather than its admissibility").

Mr. Tremp's other opinions – regarding the need for evaluations by a pain management specialist, primary care physician, physical therapist, urogynecologist, and urologist, are sufficiently based in Dr. Galloway's (admittedly broad) opinion that Plaintiff will require lifetime medical care, the medical record documenting Plaintiff's treatment and ongoing conditions, and Mr. Tremp's interview with Plaintiff. Mr. Tremp expressly acknowledges that any ongoing future treatment is dependent upon physician recommendations following those evaluations. The only Circuit Court to address life care planner testimony found no abuse of discretion where a life care planner offered projections regarding future medical needs without a physician's review "based on a review of records from the agency providing [plaintiff] with skilled nursing care, a letter from her physician, and an interview with [her] family and caregiver." *Rivera v. Turabo Med. Ctr. P'ship*, 415 F.3d 162, 170-71 (1st Cir. 2005). As cited above, other courts have permitted similar testimony. The Court is confident Defendants can address their concerns with Mr. Tremp's testimony through vigorous cross-examination.

As such, Defendants' motion to exclude Mr. Tremp's opinion is denied. (Doc. 41)

CONCLUSION

For the foregoing reasons, good cause appearing, it is hereby

ORDERED that Defendants' Motion to Strike (Doc. 101), be and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendants' Supplemental Motion for Partial Summary Judgment (Doc. 96) be, and the same hereby is, GRANTED; and it is

FURTHER ORDERED that Defendants' Motion and Supplemental Motion to Exclude the Case-Specific Opinions and Testimony of Niall Galloway, M.D. (Docs. 39, 95) be, and the same hereby are, GRANTED IN PART and DENIED IN PART as described herein; and it is

FURTHER ORDERED that Defendants' Motion to Exclude the Case-Specific Opinion and Testimony of Robert Tremp, Jr. (Doc. 41) be, and the same hereby is DENIED.

s/ *James R. Knepp II*
UNITED STATES DISTRICT JUDGE